

PHYSICIAN'S LEAFLET

PERMIXON 160 mg capsules  
Lipidosterolic extract of *Serenoa repens*. Capsules

1. COMPOSITION

ACTIVE INGREDIENT	FORMULATION
Lipidosterolic extract of <i>Serenoa repens</i> *	160 mg
EXCIPIENTS	290 mg
Polyoxethyleneglycol 10,000	

For a no. 1 capsule containing 450 mg.

Composition of the capsule covering:

Gelatin, yellow iron oxide, indigotin, titanium dioxide.

\* Containing the free and/or esterified fatty acids (97 %) and a fraction of unsaponified substances (3 %).

2. THERAPEUTIC CLASS

**Urologicals** (ATC classification): Anatomical, Therapeutic Chemical WHO Collaborating  
Centre for Drug Statistics Methodology

ATC code: **G04BX09**

3. DOSAGE FORM

Capsules.

#### 4. PHARMACOLOGICAL CHARACTERISTICS

The lipidosterolic extract of *Serenoa repens* has antiandrogenic properties which have a specific action on the target organ without causing any other hormonal incidence nor any interference with the hypothalamic-pituitary axis.

These anti-androgenic properties are due to an inhibition of both the synthesis by inhibition of the 5  $\alpha$  reductase activity and the fixation of Dihydrotestosterone (DHT) to its cytosolic receptor. Since the hormone translocation to the nucleus is made impossible, a decrease in the protein synthesis should follow. Such a decrease was shown under the effect of PERMIXON on prostatic cell cultures previously by an hormonal association of testosterone and prolactin.

Moreover, in vitro studies in animals showed that PERMIXON, through the inhibition of the phospholipase A2 activity and the release of arachidonic acid, is likely to decrease the synthesis of prostaglandins implied in the tonus and motility of walls of the lower urinary tract, and in the Hormonal interactions that have a major role in the cause of prostatic hyperplasia and inflammation.

Besides, pharmacology studies allow to show a great decongestive effect of the preparation. It is very clear on the vascular phases of the inflammation with a reduced capillary permeability. This activity is particularly interesting during evolutive flare-ups when the factor of pelvic Congestion play a major part in determining the symptomatology.

These antiandrogenic and decongestive effects could explain the results observed on the prostate.

#### 5. PHARMACOKINETICS

Pharmacokinetic studies cannot be performed with the drug of this type.

#### 6. INDICATIONS

Treatment of moderate micturation troubles related to benign hypertrophy of prostate.

#### 7. CONTRAINDICATIONS

**Pre-existing serious abdominal disorders**

#### 8. WARNINGS

Pregnancy and lactation

Not applicable.

Use in the elderly

No particular precautions.

Effects on ability to drive and use machines

None known.

9. ADVERSE REACTIONS

**Nausea, abdominal pain, diarrhea, alteration in taste and urticaria have been reported**

10. PRECAUTIONS

The drug taken on an empty stomach may sometimes cause nausea.

Drug interactions

The experimental study of PERMIXON did not allow to show any harmful interference with the therapeutic categories frequently associated in this pathology (urinary antibiotics and antiseptics, anti-inflammatory agents).

Dosage and administration

Two capsules daily taken at mealtime (one in the morning, one in the evening).

Overdosage

None known.

Shelf-life

The product is stable for 2 years.

Special precautions for storage

To be protected from heat.

PIERRE FABRE MEDICAMENT

45, place Abel Gance – 92654 Boulogne Cedex – France

**Medical information:**

PIERRE FABRE MEDICAMENT

Division Internationale

La Chartreuse – 81106 CASTRES Cedex – France

Tel. (33) 63 71 45 00

Importer: Mediline Ltd.

Ben-Gurion 22, Herzlyia